K003768

JAN - 5 2001

ALCON
ALCON Research, Ltd.
6201 SOUTH FREEWAY
FORT WORTH, TEXAS 76134
(817) 293-0450

December 5, 2000

510(k) SUMMARY

Submitted by:

Sherri J. Lakota
Manager, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134
(817) 568-6179 (Phone)
(817) 551-4630 (Fax)

Trade Name:	MONARCH®[1] II IOL Delivery System
Common Name:	IOL Delivery System
Classification Name:	Intraocular Lens Guide, 21 CFR 886.4300

[1] MONARCH® is a registered trademark of Alcon Laboratories, Inc.

1. Predicate Device

The predicate device to which we are claiming equivalence is:

a. MONARCH II IOL Delivery System (Alcon Research, Ltd.)

2. Device Description

The MONARCH II IOL Delivery System consists of two parts: an autoclavable, reusable titanium handpiece and a sterile, single-use cartridge. It is a device used for folding and deliverying ACRYSOF®[2] intraocular lenses into the eye for replacement of the human crystalline lens. The system provides a controlled means to reliably place the ACRYSOF intraocular lens into the capsular bag.

3. Intended Use of the Device

The intended use of this device is to fold and deliver Alcon ACRYSOF intraocular lenses into the eye for replacement of the human crystalline lens.

4. Summary of the Technological Characteristics of the Device

The MONARCH II IOL Delivery System utilizes a sterile, single use cartridge and a reusable handpiece to deliver ACRYSOF lenses. The cartridge with enhanced lubricity is designed for easy loading and reliable folding of ACRYSOF lenses. The handpiece accepts the cartidge and delivers the lens by using a plunger to express the lens. The plunger head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by a screw mechanism to ensure a smooth and well controlled lens delivery.

5. Summary of the Performance Data

The performance tests for the Monarch II IOL Delivery System will demonstrate that it can be used to deliver ACRYSOF IOLs without adversely affecting the overall shape, power, resolution or cosmetic attributes of the lenses.

6. Conclusions

The results of the nonclinical performance testing will be subjected to particular pass criteria that will support claims of substantial equivalence.

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[2] ACRYSOF® is a registered trademark of Alcon Laboratories, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Ms. Sherri J. Lakota
Manager, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K003768
Trade Name: Monarch II IOL Delivery System, Cartridges A and C
Regulatory Class: I, Reserved
Product Code: 86 MSS
Dated: December 5, 2000
Received: December 6, 2000

Dear Ms. Lakota:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indication for Use

510(k) Number (if known): K003768

Device Name: MONARCH® II IOL Delivery System

Indications For Use:

The intended use of this device is to fold and deliver Alcon ACRYSOF® intraocular lenses into the eye for replacement of the human crystalline lens.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joel P. Glon

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003768

(Optional Format 3-10-98).